REMARKS

Claims 26-50 and 66-68 are pending in this application. In a previous amendment, claims 32-56 were amended as claims 26-50 to correct the numbering and Claims 57-65 were cancelled.

Applicants have amended claims 26 and 40 to clarify that the mycobacterial DNA (B-DNA) is obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA. Support for these amendments appears throughout the specification, particularly at pages 4, 8, 11-12, and 14. Applicants have also rewritten claims 36 and 48 in independent form and note that these claims were not rejected under 35 USC § 102 over the Morales reference.

Finally, Applicants have added newly presented claims 66- 68 which recite ranges of amounts of the M-DNA in the compositions to be administered. Support for newly presented claims appears in the specification at page 13. No new matter has been added.

Rejection under 35 U.S.C. § 102 (b)

The Examiner has rejected Claims 26-35, 38-47, 49-56 under 35 U.S.C. § 102 (b) as being anticipated by Morales et al., J. Urology, 153:1706-10 (1995) (hereinafter referred to as "Morales."). The Examiner asserts that Morales teaches a method of treating prostate cancer by administering a composition of mycobacterial DNA (B-DNA) from *M. phlei* and a pharmaceutically acceptable carrier (such as oil microdroplets) to an animal having cancer in an amount effective to have an antineoplastic effect on prostate cancer. Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

First, the Morales reference fails to teach or suggest a method of treating prostate cancer by administering a composition comprising mycobacterial DNA (B-

DNA). The Morales reference discloses only the use of mycobacterial *cell walls* for its treatment, not the use of mycobacterial DNA. Specifically, the Morales reference does not disclose a method for treating prostate cancer that comprises administration of a composition comprising mycobacterial DNA that is obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA, as recited by the presently-submitted claims.

The Examiner's position, however, is that the *M. phlei* call wall described by the Morales reference would *inherently* have the cell's DNA preserved and complexed to the cell wall unless the cell wall was specifically treated to remove the DNA. Applicants disagree. One of ordinary skill in the art would not expect a composition comprising genetic matter to function in a way that is similar to a composition comprising cell wall contents. This is particularly the case when the desired end result is to treat a disease as elusive as cancer. Those of ordinary skill in the art are aware that the field of cancer treatment is not composed of predictable or reliable treatments.

However, without conceding to the correctness of the Examiner's assertion and in the interest of advancing the prosecution of this case, Applicants have amended the claims to clarify that the mycobacterial DNA is obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA. In other words, the claims clarify that specific measures are taken in order to at least partially preserve the DNA and ensure that it is present. Such measures are not suggested or disclosed by the Morales reference. In fact, the Morales reference does not use, suggest, or describe DNAase-free reagents, nor does it describe any benefit of using DNase-free reagents for the purpose of at least partially preserving mycobacterial DNA. There is no mention of efforts to maintain or preserve the DNA or any nucleic acids of the mycobacterium used in the Morales reference.

And as previously explained, inherency may not be established by probabilities or possibilities. *See In re Oelrich and Divigard*, 212 U.S.P.Q. 323

(C.C.P.A. 1981). The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *See id.* As such, Applicants respectfully submit that presently-submitted independent claims 26 and 40 and all claims depending therefrom are patentable in light of the Morales reference.

Second, with respect to claims 29-32, the Morales reference does not teach that mycobacterial cell walls or *M. phlei* cell walls can be pharmaceutically acceptable carriers for *M. phlei* DNA. Rather, Morales teaches that oil microdroplets are the pharmaceutically acceptable carrier for *M. phlei* cell walls. As such, the is no suggestion or disclosure in the Morales reference that anticipates each and every element of these claims, which specifically recite that the pharmaceutical carrier comprises a mycobacterial cell wall or an *M. phlei* cell wall.

Thus, in light of the amendments and remarks submitted with this response, Applicants respectfully submit that the 35 U.S.C. § 102(b) rejections made over the Morales reference should be withdrawn and that the claims as presently-submitted are in condition for allowance.

Rejection under 35 U.S.C. § 103 (a)

The Examiner has rejected Claims 26-59 (Applicants believe that the Examiner intended to reject claims 26-50) under 35 U.S.C. § 103 (a) as being unpatentable over Morales in view of Filion et al., Blood, 90(10), Suppl. 1:p.58B (1997) (hereinafter referred to as "Filion."). The Examiner has characterized Morales as described above, but admits that Morales does not teach that administration comprises the administration of an immunological agent or that the antineoplastic effect is induction of a cytokine, such as IL-12. The Examiner states, however, that Filion teaches that *M. phlei* cell wall complex is an antitumoral agent that induces IL-12 synthesis when injected into mice. The Examiner asserts that it would have been obvious to one of ordinary skill in the art to use the method of Morales to induce IL-12 production in animals with prostate cancer since Filion teaches that *M. phlei* cell

wall complex can induce IL-12 synthesis and thus is an immunological agent. Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

First, the Morales reference and the Filion reference are not properly combinable. The Filion reference does not teach or suggest treatment of prostate cancer. It merely discusses compositions that have "anti-tumor activity" without suggesting what type of tumor can be treated. However, as discussed above, the field of cancer treatment is highly unpredictable. It is not uncommon for a particular therapeutic regimen to be effective only for certain cancers, and many times for only certain patients. Those of ordinary skill in the art would understand that the teaching of a particular therapeutic composition for a particular cancer would not necessarily lead to one to assume that the same composition would be effective for the treatment of another cancer.

Accordingly, the discussion in the Filion reference discussing the use of an emulsion containing mycobacterial cell wall complex derived from *M. phlei* having anti-tumor activity does not suggest that the use of the emulsion would be effective to treat prostate cancer, as presently-claimed. For the same reason, there would be no motivation for one of ordinary skill in the art to combine the Morales reference, specifically directed to treating adenocarcinoma of the prostate, with the Filion reference, which does not suggest treatment of prostate tumors. As such, the rejection combining these references should be withdrawn.

Moreover, even if the Morales and Filion references were properly combinable, their combination would not result in the presently-claimed invention. The method taught by Morales does not disclose the use of mycobacterial DNA for treating prostate cancer and Filion does not mention the treatment of prostate cancer at all. Additionally, neither reference teaches or suggests a method of treating prostate cancer that includes the use of mycobacterial DNA obtained from a disrupted

mycobacterium using DNase-free reagents in order to at least partially preserve the DNA.

Thus, in light of the amendments and remarks submitted with this response, Applicants respectfully submit that the 35 U.S.C. § 103(a) rejections combining the Morales and Filion references should be withdrawn and that the presently-submitted claims are in condition for allowance.

CONCLUSION

For at least the above reasons, Applicants respectfully request allowance of claims 26-50 and 66-68 and issuance of a patent containing these claims in due course. If there remain any additional issues to be addressed, the Examiner is urged to contact the undersigned attorney.

PETITION FOR EXTENSION OF TIME

Pursuant to 37 C.F.R. 1.136(a), Applicants petition that the period for response to the Office Action dated October 22, 2002 in connection with the above-identified application be extended for two months, to and including March 22, 2003 (which is a Saturday). A check for this fee is enclosed. The Commissioner is hereby authorized to charge any additional fees or credit any overpayment to Deposit Order Account No. 11-0855.

Respectfully submitted,

Kristin D. Mallatt
Reg. No. 46,895

OF COUNSEL:

KILPATRICK STOCKTON LLP
1100 Peachtree Street
Suite 2800
Atlanta, Georgia, 30309-4530
404.815.6147